DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office
95091d

60 8th Street, N.E.
Atlanta, Georgia 30309

November 1, 2004

VIA FEDERAL EXPRESS

Douglas Armistad
Owner
ABC Compounding Company, Inc.
6970 Jonesboro Road
Morrow, Georgia 30260

WARNING LETTER
(05-ATL-03)

Dear Mr. Armistad:

Investigator Leah M. Andrews of this office conducted an initial inspection of your drug manufacturing facility between July 22 and August 12, 2003. A follow-up inspection was conducted by Investigator Andrews on April 19 & 29, 2004. These inspections covered the manufacture of your antibacterial hand soaps, cleaners, and sanitizers and included the following products:

QS Plus Instant Hand Sanitizer
aero® Sani Peach Antibacterial Hand Cleaner
aero® Sani MANGO Antimicrobial Hand Cleaner
aero® Foamy MANGO HAND CLEANER
aero® Santi-Wash Hand Soap
aero® Palm Antibacterial Hand Soap
[redacted]**MEDICATED LOTION SOAP**
HAND AID Instant Hand Sanitizer

During these inspections, information and labeling were obtained for these products, which are being manufactured and marketed by your firm for over-the-counter (OTC) distribution. Based on the information and labeling obtained, these products are intended for use in killing or reducing the number of pathogenic microorganisms on the skin to prevent the diseases caused by them. Accordingly, these products are "drugs" as defined by section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). Their marketing in the United States violates one or more provisions of the Act as follows:

QS Plus Instant Hand Sanitizer

This product's labeling identifies "benzethonium chloride USP" as the "Active Ingredient" and includes the statements: "REQUIRES NO WATER," "requires no soap or water," "KILLS 99.99% OF MOST COMMON GERMS THAT CAUSE ILLNESS IN AS LITTLE AS 15 SECONDS," and "[r]ub hands together until dry. Use as needed between hand washes to help reduce bacteria on the skin." These statements represent that this product is an effective alternative to soap-and-water hand washing in reducing bacteria on the skin and that it does not require a water rinse after use.

We are not aware that a product, formulated and labeled like this one, was marketed in the United States on or before December 4, 1975, nor is this product the subject of a final determination by FDA under Title 21 of the Code of Federal Regulations (CFR), Section 330.14 (21 CFR § 330.14). Therefore, QS Plus Instant Hand Sanitizer is not included in FDA's OTC Drug Review. Nor are we aware of any data establishing that this drug is generally recognized as safe and effective for its labeled uses. It is, therefore, a "new drug" as defined by section 201(p) of the Act. Since QS Plus Instant Hand Sanitizer is not the subject of an approved new drug application, its marketing in the United States violates section 505(a) of the Act.

For your information, FDA is currently evaluating the safety and effectiveness of benzethonium chloride-containing antibacterial cleansers under the agency's OTC Drug Review and antibacterial cleansers containing this ingredient are included in the review so long as they are intended to be rinsed with water after use and they are not offered as an alternative to soap-and-water hand washing (see 59 Federal Register (FR) 31402, June 17, 1994).

aero® Sani Peach Antibacterial Hand Cleaner
aero® Sani MANGO Antimicrobial Hand Cleaner
aero® Foamy MANGO HAND CLEANER

As noted above, a monograph for OTC topical antibacterial/antimicrobial drug products like these is being developed under FDA's OTC Drug Review (see 59 FR 31402, June 17, 1994). Pending issuance of a final monograph, these OTC drug products are subject to all existing requirements affecting their manufacturing, packaging, and labeling, including the requirement for adequate directions for use to appear on the labeling. These three products bear absolutely no directions for the antibacterial/antimicrobial uses described in their labeling, and they are not exempt from this requirement. Therefore, they are misbranded under section 502(f)(1) of the Act as further described by 21 CFR § 201.5.

aero® Santi-Wash Hand Soap

The label for this product identifies "Iodine" as the "Active Ingredient." Other statements on the label claim that the product is "based on an iodophor complex" and that it

"**Contains: Iodine Complex.**" These statements suggest that the iodine contained in the product is actually present in the form of an iodine complex. The inspections of your facility disclosed that this complex is alpha-(p-nonylphenyl)omega hydroxypoly (oxyethylene)-iodine complex. This complex is the active ingredient, as defined by 21 CFR § 201.66(b)(2), in **aero®** Santi-Wash Hand Soap and should be declared by this established name on the label. Because this complex is not declared on the label by this established name, this product is misbranded under section 502(e)(1)(A)(ii) of the Act.

aero® Sani Peach Antibacterial Hand Cleaner
aero® Palm Antibacterial Hand Soap
[redacted]**MEDICATED LOTION SOAP**

The label for **aero®** Sani Peach Antibacterial Hand Cleaner identifies "PCMX (Para-chloro-meta-xylenol)" as its "Active Ingredient." The label for **aero®** Palm Antibacterial Hand Soap identifies "Parachlorometaxylenol" as its "ACTIVE INGREDIENT," and the label for [redacted] **MEDICATED LOTION SOAP** identifies "Parachlorometaxylenol (PCMX)" as its "**ACTIVE INGREDIENT.**" The established name for the active ingredient in each of these products is chloroxylenol. Therefore, all three products are misbranded under section 502(e)(1)(A)(ii) of the Act.

As noted previously, OTC antibacterial/antimicrobial cleansers are being evaluated under FDA's OTC Drug Review. The tentative final monograph (TFM) for these products was published in the Federal Register of June 17, 1994. This TFM is available at http://www.fda.gov/cder/otcmonographs/Antimicrobial/antimicrobial_antiseptic_TF_PR_19940617.pdf. As explained above, products like QS Plus Instant Hand Sanitizer, are not included in this TFM.

FDA does not object to the marketing of products that comply with the formulation and labeling requirements described in TFMs, along with any other regulations affecting these products. Marketing products in conformance with a TFM, however, is subject to the risk that a final monograph or rule may require reformulation and/or relabeling, or FDA approval pursuant to section 505 of the Act.

In addition, FDA's most recent inspection of your facilities revealed several continuing significant deviations from the Current Good Manufacturing Practice (CGMPs) regulations under 21 CFR Parts 210 and 211. These CGMP deviations, described below, cause your drug products to be adulterated under section 501(a)(2)(B) of the Act.

You have failed to establish an adequate stability testing program to determine appropriate expiration dates for all your drug products (21 CFR § 211.166(a) and (b)). You do not have sufficient stability data to assure that your drugs meet applicable standards of strength, quality, and purity at time of use. See generally 21 CFR § 210.1(a). Currently the requirement for an expiration date is not being enforced for OTC drug products if they are stable for at least three years, as supported by appropriate stability data. See 21 CFR § 211.137(h). Review of your stability data revealed that you do not have sufficient data to support the lack of expiration dates

on the labels for **aero®** Santi-Wash Hand Soap and **HAND AID Instant Hand Sanitizer**.

The product **aero®** Santi-Wash Hand Soap is labeled as containing 0.32% iodine. Our previous inspection found that the only available stability data for this product indicated a decrease in assay to 48 – 55% (of label claim) after three years, 56 – 65% after two years, and 65 – 67% after one year. Only one lot of this product has been tested for stability since 1999 and that was as a result of our previous inspection in 2003. That data provide only eight months of stability for this product.

The three year stability test results for **HAND AID Instant Hand Sanitizer** indicate that it fails to meet your release specifications after three years. During the current inspection you did provide some additional information that indicates stability of one lot of this product at two years and nine months. While this singular lot provides positive information regarding the product's stability, earlier stability lots failed, i.e., the assay results at three years were actually higher than the initial assay results. FDA notes that you did not investigate why the earlier stability lots failed as required by 21 CFR § 211.192. Until the reason for these questionable results is determined, a problem with the product, the manufacturing process, and/or the analytical method cannot be ruled out.

You have failed to investigate failures of a batch or any of its components to meet their specifications (21 CFR § 211.192). FDA notes that you do not maintain any written records regarding unexplained discrepancies and batch failures as required by 21 CFR § 211.192. Further, you do not have any written procedures requiring such an investigation as required by 21 CFR § 211.22(d). Our inspections revealed that batches are routinely reprocessed when initial release specifications fail. All [redacted] batches of **aero®** Palm Antibacterial Hand Soap manufactured in 2003 had an initial out-of-specification viscosity result. Three out of [redacted] batches of **aero®** Santi-Wash Hand Soap were reprocessed after an initial assay failure for iodine. In addition, none of the stability failures, described above, were the subject of an investigation as required by 21 CFR § 211.192. The most recent failure was an out-of-specification result for the active ingredient chloroxylenol in [redacted] **MEDICATED LOTION SOAP** manufactured in March 2004. You reworked the lot without performing an investigation regarding the out-of-specification result as required under 21 CFR § 211.192. You have not established written procedures for the reprocessing of batches to ensure that they will conform to all established specifications (21 CFR § 211.115).

The CGMP deviations described above were included on the Inspectional Observations forms (FDA 483) which were issued to and discussed with Michael Rekhelman, Vice President of Technical Services, at the conclusion of the inspections. Copies of the FDA 483s are enclosed for your review.

The violations described above are not meant to be all-inclusive. It is your responsibility to ensure that all drug products manufactured and distributed by your firm comply with the Act. Federal agencies are advised of the issuance of all Warning Letters pertaining to drugs and devices so that they may take this information into account when considering the award of contracts. We request that you take action immediately to correct these violations. Failure to do

so may result in regulatory action without further notice, including seizure and/or injunction.

Please send a written response to this office within fifteen working days of receipt of this letter. Your response should describe the specific actions that you will take, or have taken, to correct the violations described in this letter. Your response should also include an explanation of each step being taken to prevent recurrence of similar violations. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which corrections will be completed. Your response should be sent to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead. If you wish to discuss this letter or our continuing concerns with your facility, you should contact Mr. Campbell at (404) 253-1280.

Sincerely yours,

Mary Woleske

Mary H. Woleske, Director
Atlanta District

Enclosures